CLAIMS

We claim,

1. A method of treating neointimal hyperplasia in a subject in need thereof, comprising administering an interleukin-1 (IL-1) antagonist to the subject such that neointimal hyperplasia is treated.

2. The method of claim 1, wherein the neointinal hyperplasia is restenosis.

3. The method of claim 1, wherein the neointimal hyperplasia is atherosclerosis.

4. The method of claim 1, wherein the neointimal hyperplasia is vascular access dysfunction.

5. The method of claim 1, wherein the neointimal hyperplasia is caused by surgical stenting, angioplasty, or vascular grafting.

6. The method of claim 1, wherein the IL-1 antagonist blocks IL-1 activity or expression.

7. The method of claim 6, wherein the IL-1 antagonist is selected from the group consisting of an anti-IL-1 antibody or antibody fragment, an anti-IL-1R1 antibody or antibody fragment, an antiIL-1RAcp antibody or antibodyfragment, an IL-1 trap, IL-1Ra, an antisense molecule, an inhibitory ribozyme designed to catalytically cleave gene mRNA transcripts encoding IL-1α, IL-1β, IL-1R1, IL-1RAcp, and a short interfering RNA (siRNA) molecule.

8. The method of claim 7, wherein the IL-1 trap comprises (i) one or more IL-1 receptor components or fragments thereof, (ii) one or more antibody or antibody fragments specific to an IL-1 ligand or an IL-1 receptor, or fragments thereof, or a combination of receptor components and antibody fragments, and (iii) a multimerizing component.

9. The method of claim 8, wherein the multimerizing component is an immunoglobulin-derived domain.

10. The method of claim 1, wherein the subject is a human.

11. The method of claim 1, wherein the administration is subcutaneous, intramuscular, intranasal, intraarterial, intravenous, topical, transvaginal, transdermal, transanal administration or oral routes of administration.

12. A pharmaceutical composition comprising an IL-1 antagonist and a pharmaceutically acceptable carrier.

13. The pharmaceutical composition of claim 12, wherein the IL-1 antagonist blocks IL-1 activity or expression.

14. The pharmaceutical composition of claim 13, wherein the IL-1 antagonist is selected from the group consisting of an anti-IL-1 antibody or antibody fragment, an anti-IL-1R1 antibody or antibody fragment, an antiIL-1RAcp antibody or antibody fragment, an IL-1 trap, IL-1Ra, an antisense molecule, an inhibitory ribozyme designed to catalytically cleave gene mRNA transcripts encoding IL-1α, IL-1β, IL-1R1, IL-1RAcp, and a short interfering RNA (siRNA) molecule.

15. The pharmaceutical composition of claim 14, wherein the IL-1 trap comprises (i) one or more IL-1 receptor components or fragments thereof, (ii) one or more antibody or antibody fragments specific to an IL-1 ligand or an IL-1 receptor, or fragments thereof, or a combination of receptor components and antibody fragments, and (iii) a multimerizing component.

16. The pharmaceutical composition of claim 15, wherein the multimerizing component is an immunoglobulin-derived domain.

17. A method of preventing neointimal hyperplasia in a subject in need thereof, comprising administering a cytokine antagonist to the subject such that neointimal hyperplasia is prevented.

18. The method of claim 17, wherein the neointinal hyperplasia is restenosis, atherosclerosis, or vascular access dysfunction.

19. The method of claim 18, wherein the neointimal hyperplasia is caused by surgical stenting, angioplasty, or vascular grafting.

20. An article of manufacturing, comprising:

(a) packaging material; and

(b) a pharmaceutical gent contained within the packaging materi9al;

wherein the pharmaceutical agent comprises at least one interleuking-1 (IL-1) trap of the invention and wherein the packaging material comprises a label or package insert which indicates the IL-1 trap can be used for the treatment of neointimal hyperplasia.